REMARKS

Claims 1- 21 were presented when the instant application was filed. Subsequently, in a response to a restriction requirement, Applicants elected to prosecute Claims 1-15 of Group I, and canceled Claims 16-21 without prejudice to their future prosecution. Thus Claims 1-15 are currently pending. In the Final Office Action, the Examiner has raised a number of issues, which are set forth by number in the order they are herein addressed:

1) Claims 7 and 15 are rejected under 35 USC § 112, second paragraph, as allegedly being indefinite; and

2) Claims 1-15 are rejected under 35 USC § 102(e) as allegedly being anticipated by Straus (US Publication No. 2002/0086289 A1) as evidenced by DeRisi *et al.* (Science 278:680-686, 1997).

Applicants hereby amend Claims 7 and 15, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments. Applicants reserve the right to prosecute the original, similar, or broader Claims in one or more future application(s). These amendments do not introduce new matter and are not intended to narrow the scope of any of the claims within the meaning of *Festo*.[1]

1) The Claims Are Definite

The Examiner has rejected Claims 7 and 15 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite. The Examiner states:

> it is not clear whether claims 7 and 15 are further limiting of the previously recited "target signal," the previously recited "reference signal," or both. Clarification is required (Final Office Action, pages 2 and 3).

Applicants respectfully disagree that the claims are indefinite. Nonetheless, Applicants have amended Claims 7 and 15, in order to further the prosecution of the present application and Applicants' business interests, yet without acquiescing to the Examiner's arguments, and while reserving the right to prosecute the original, similar, or broader claims in one or more future application(s). Specifically, Applicants have amended Claims 7 and 15 to recite "wherein said target signal and said reference signal comprise fluorescence." Support for this amendment is found for instance in Examples 2 and 3, which teach labeling target DNA with Cy3-dCTP and reference DNA with Cy5-dCTP (fluorescent labels), and then measuring the respective fluorescence signals after hybridization to an array (Specification, beginning on page 33 at line 6,

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[1] *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 122 S.Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002).

and ending on page 37 at line 15). As the amended claims are definite, Applicants respectfully request that this rejection be withdrawn.

2) The Claims Are Novel

The Examiner has rejected Claims 1-15 under 35 U.S.C. § 102(e), as allegedly being anticipated by Straus (US Publication No. 2002/0086289 A1) as evidenced by DeRisi *et al.* (Science 278:680-686, 1997). The Examiner reiterated the anticipation rejection from the prior Office Action:

> Straus discloses a method for identifying bacteria in which labeled target DNA from a test sample including bacteria is hybridized to a "detection ensemble". . . Straus further discloses both the combination of positive and negative control probes with test sample molecules prior to hybridization (see, e.g., page 19), and preparation of a database of fingerprints with which test sample patterns may be compared (see, e.g., page 28). . . It is again noted that Straus (at, e.g., page 19) clearly teaches the simultaneous hybridization of test and positive control molecules. While it is acknowledged that the method of Straus employs multiple hybridization steps, the instant claims recite the open transitional language "comprising," and therefore clearly encompass methods including any type of additional steps, including additional hybridization steps. Further, Applicants' specification does not include, e.g., a limiting type of definition for the term "co-hybridizing" or "co-hybridization" that would exclude the hybridization practiced by Straus (Final Office Action, pages 3-5).

Applicants respectfully disagree that the pending claims are anticipated by Straus, and remind the Examiner that a "claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."[2] In contrast to the claimed invention, Straus does not teach **hybridizing labeled target DNA to array elements on a solid support or microchip**. As clearly shown in Figure 5 and as described in Step 4 of the disclosed genomic profiling method (Straus, paragraph 0146), Straus teaches the *unordered deposition of unlabeled test (sample) DNA* to a solid support, which is then used in Step 5 to positively select *unlabeled reference (ensemble of ID probes) DNA* by hybridization in a process termed sample-selection (Straus, paragraph 0147). It is only the positively-selected reference DNA that is subsequently amplified, labeled and hybridized to the array elements (detection ensemble) as described in Steps 6 and 7 of Straus' method (Straus, paragraphs 0148 and 0149). Importantly, *the sample DNA of Straus is neither labeled nor hybridized to the arrayed elements (detection array)* as required by the pending claims.

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[2] *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Moreover, the inclusion of positive and negative control probes in Straus' subtractive hybridization method is irrelevant, since it is the ensemble of ID probes and not the controls that are comparable to the claimed **reference DNA from at least four strains of reference bacteria,** utilized in Applicants' competitive hybridization methods. Straus clearly distinguishes the controls from the reference DNA by disclosing that:

> [b]oth positive and negative controls can be included with an ensemble of ID probes (Straus, paragraphs 0178-0180).

Likewise, Applicants distinguish the controls from the reference DNA by teaching:

> "[m]ixtures of genomic DNA (1 μg) from the four reference strains (1:1:1:1) used for microarray fabrication were labeled . . . and used as reference DNA for signal ratio calculation. . . Yeast gene *STE* (10 ng) was included in each labeling reaction as a positive control, as well as an internal standard (Specification, at page 33, lines 12-16).

Thus, even with the open transitional language "comprising," the "cohybridizing" **both** target and reference DNA to arrayed elements" step of Claims 1 and 9, does not encompass both hybridization steps of Straus (Step 5 hybridization of reference DNA to immobilized target DNA, and Step 7 hybridization of a fraction of the reference DNA to immobilized array elements). Accordingly, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants believe the amendments and arguments set forth above traverse the Examiner's rejections and, therefore, request that a timely Notice of Allowance be issued in this case. However, should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect.

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